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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D0918536 | <b>(X3) Date Survey Completed</b><br><br>01/05/2021 |
| <b>Name of Provider or Supplier</b><br><br>Razmik Ohanjanian, Md, Inc  | <b>Street Address, City, State</b><br><br>511 Western Ave, Glendale, CA    |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D2087</b>              | <p>ROUTINE CHEMISTRY<br/>CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the American Proficiency Institute (API) proficiency testing records and interview with the testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for multiple chemistry analytes for the years 2019 and 2020. The finding included: 1. Based on review of PT records for 2019 and 2020, API reported the following unsatisfactory scores for the following analytes: Analyte Event Score Reported ALT (SGPT) Q1-2019 60% ALT (SGPT) Q1-2020 60% AST (SGOT) Q3-2020 60% Total Bili Q1-2020 60% HDL Cholesterol Q1-2019 40% Creatine Q3-2020 60% T4 Thyroxine Q2-2020 60% 2. Based on the laboratory testing declaration submitted at the time of the survey on 01/05/2020 the laboratory analyzed and reported approximately 15,300 Routine Chemistry tests for each year during the time the laboratory had unsatisfactory proficiency testing results. 3. The TP affirmed 01/05/2020 at approximately 1:30 p.m. that the laboratory received the above unsatisfactory proficiency testing scores</p> |
| <b>D2098</b>              | <p>ENDOCRINOLOGY<br/>CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:</p>   |

Based on reviews second quarter (Q2-2020) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the laboratory testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for T4 (Thyroxine) analyte. The findings included: 1. Q2-2020, API reported an unacceptable score of 60% for T4 analyte. 2. For five (5) out of five (5) random patient sampling test results reviewed covering period from 03/27/2020 to 08/27/2020, the laboratory analyzed and reported an unknown number of T4 quantitative tests during the period the laboratory received the unsatisfactory proficiency testing score. 3. The TP confirmed on 01/05 /2021 at approximately 1:40 p.m. that the laboratory received the above unsatisfactory proficiency testing score for T4.

**D3001**

**FACILITIES**  
CFR(s): 493.1101(a)(1)

The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory testing area and interview with the testing personnel (TP), it was determined that the laboratory testing area failed to be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the clinical testing process. The findings included: 1. The laboratory area consist of a small room (approximately 200-300 square feet) which serves to house the automated testing instruments: Beckman Coulter for Hematology testing, the Chemistry analyzer, and the Immunolite 1,000; the testing personnel's office, as well as storage area for reagents, documents, and patients' results and data. 2. The space designated for the laboratory appears to be insufficient. The room is crowded, difficult to maintain, inappropriate for proper traffic flow, and fails to provide sample integrity and quality for testing, in addition to increase risk of contamination of paperwork and possible cross-contamination of samples. 3. The TP affirmed on January 5, 2021 at approximately 2:00 p.m. that the laboratory failed to be constructed, arranged and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. 4. The laboratory's testing declaration form, signed by the laboratory director on January 5, 2021, stated that the laboratory performs approximately 19,300 tests annually.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on the lack of laboratory written policies and procedures and interview with the testing personnel (TP), it was determined that the laboratory failed to have available and follow written procedures for Hematology, Endocrinology and Routine Chemistry test procedures performed in the laboratory. The findings included: 1. On the day of the survey 01/05/2021 at approximately 1:30 p.m. the laboratory failed to provide

written policies and procedures for Hematology, Endocrinology, and Routine Chemistry for the test procedures performed in the laboratory. 2. For ten (10) out of ten (10) random patient test results reviewed covering period from 08/23/2018 to 08/27/2020, all the patients had tests ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The TP confirmed on 01/05/2021 at approximately 2:00 p.m. that the laboratory did not have written policies and procedures available for Hematology, Endocrinology, and Routine Chemistry test performed in the laboratory.

**D6010**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(2)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:  
Based on direct observation of the laboratory operation, test performance, documents and reagent storage, and interview with the testing personnel; it was determined that the laboratory director failed to ensure that the physical plant, space, organization, and environmental conditions of the laboratory are appropriate for the testing performed. See D3001.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:  
Based on direct observation and interview with the laboratory testing personnel it was determined that the laboratory director failed to ensure that an approved procedure manual is available at all times to all personnel responsible for any aspect of the testing process. See D5041.